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Trends in Permanent Pacemaker Implantation in the United States From 1993 to 2009

Increasing Complexity of Patients and Procedures

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Objectives This study sought to define contemporary trends in permanent pacemaker use by analyzing a large national database.

Background The Medicare National Coverage Determination for permanent pacemaker, which emphasized single-chamber pacing, has not changed significantly since 1985. We sought to define contemporary trends in permanent pacemaker use by analyzing a large national database.

Methods We queried the Nationwide Inpatient Sample to identify permanent pacemaker implants between 1993 and 2009 using the International Classification of Diseases-Ninth Revision-Clinical Modification procedure codes for dual-chamber (DDD), single-ventricular (VVI), single-atrial (AAI), or biventricular (BiV) devices. Annual permanent pacemaker implantation rates and patient demographics were analyzed.

Results Between 1993 and 2009, 2.9 million patients received permanent pacemakers in the United States. Overall use increased by 55.6%. By 2009, DDD use increased from 62% to 82% ($p < 0.001$), whereas single-chamber ventricular pacemaker use fell from 36% to 14% ($p = 0.01$). Use of DDD devices was higher in urban, nonteaching hospitals (79%) compared with urban teaching hospitals (76%) and rural hospitals (72%). Patients with private insurance (83%) more commonly received DDD devices than Medicaid (79%) or Medicare (75%) recipients ($p < 0.001$). Patient age and Charlson comorbidity index increased over time. Hospital charges ($2011) increased 45.3%, driven by the increased cost of DDD devices.

Conclusions There is a steady growth in the use of permanent pacemakers in the United States. Although DDD device use is increasing, whereas single-chamber ventricular pacemaker use is decreasing. Patients are becoming older and have more medical comorbidities. These trends have important health care policy implications. (J Am Coll Cardiol 2012;60:1540–5) © 2012 by the American College of Cardiology Foundation

Implantation of cardiac pacemakers in the United States has increased (1–3). Pacemaker technology has advanced from fixed-rate single-chamber pacemakers to dual-chamber pacemakers with pacing algorithms to enhance rate response and to minimize ventricular pacing. Despite these advancements, the National Coverage Determination for Cardiac Pacemakers, published by the Centers for Medicare and Medicaid Services, has not changed significantly since 1985 (4). We evaluated cardiac pacemaker implantation trends in the United States to assess the disparity between National Coverage Determination policies, which emphasized the role of single-chamber pacing, and contemporary medical practice.

Methods

The Nationwide Inpatient Sample (NIS) was queried to identify patient demographics, health risk profile, and health economic data for pacemaker patients between 1993 and 2009 using the International Classification of Diseases-Ninth Revision-Clinical Modification. The annual NIS is a statistically valid annual survey of approximately 20% of hospitalizations in the United States, regardless of payment source. The type of pacemaker implanted was characterized as either a dual-chamber (DDD) pacemaker, single-chamber

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ventricular (VVI) pacemaker, single-chamber atrial (AAI) pacemaker, or biventricular (BiV) pacemaker. For the present study, we used the International Classification of Diseases-Ninth Revision-Clinical Modification codes for DDD (37.83), VVI (37.81–82, 37.71), AAI (37.81–81, 37.73), or BiV (00.51) devices. Trends for sinus node dysfunction patients were analyzed using diagnosis codes 427.8 and 427.6.

The severity of comorbidities was characterized by the Charlson comorbidity index (CCI), which consists of 19 different disease comorbidity categories, weighted to yield a total score (5). The CCI has previously been validated as a predictor of mortality in patients with a pacemaker (3).

Statistical analyses of the NIS records with the relevant surgical codes were conducted using SAS software version 9.2 (SAS Institute, Cary, North Carolina). Hospital charges for the study period were adjusted to the equivalent amount in January 2011 using the consumer price index for medical services published by the Bureau of Labor Statistics. The sampling weights and the stratified sampling design of the NIS were taken into consideration when computing summary statistics and standard errors of these estimates. The number of surgeries performed for a particular demographic group is a positive integer and is assumed to follow a Poisson distribution. A regression model was used to estimate the surgery rate and was normalized by the size of the population and by evaluation of the calendar year trend. The surgery rate was adjusted by age, sex, race, and census regions to accommodate differences in the prevalence among demographic subpopulations. The patient health profile was calculated for each year, and linear regression was used to test for changes over time. The type of hospital performing pacemaker surgery was divided into urban nonteaching, urban teaching, and rural. The distribution of pacemaker surgery was analyzed for both type of hospital and type of insurance (private vs. Medicaid vs. Medicare).

Abbreviations and Acronyms

AAI = single-chamber atrial pacemaker

BiV = biventricular pacemaker

CCI = Charlson comorbidity index

DDD = dual-chamber pacemaker

NIS = Nationwide Inpatient Sample

VVI = single-chamber ventricular pacemaker

Results

Between 1993 and 2009, 2.9 million patients received a permanent pacemaker in the United States. During this time, overall use increased by 55.6%, from 121,300 in 1993 to 188,700 in 2009. This represents 46.7 implantations per 100,000 persons in 1993, which increased to 61.6 implantations per 100,000 persons in 2009 (Fig. 1). Although DDD pacemakers increased annually from 29.1/100,000 to 50.4/100,000 ($p < 0.0001$), VVI pacemakers decreased from 17.2/100,000 to 8.7/100,000 ($p = 0.01$). By 2009, DDD use increased from 62% to 82% of all implants ($p < 0.001$), while VVI use decreased from 36% to 14% ($p = 0.01$). Although AAI use remained constant at 1%, BiV pacemaker use increased to 4% in 2009 from a base in 2001.

Demographic trends. The impact of gender on pacemaker use was analyzed. During the study period, DDD pacemakers were implanted in 77.3% of men, whereas 20.1% received VVI pacemakers, 0.5% received AAI pacemakers, and 1.9% received BiV pacemakers. By contrast, 76.8% of

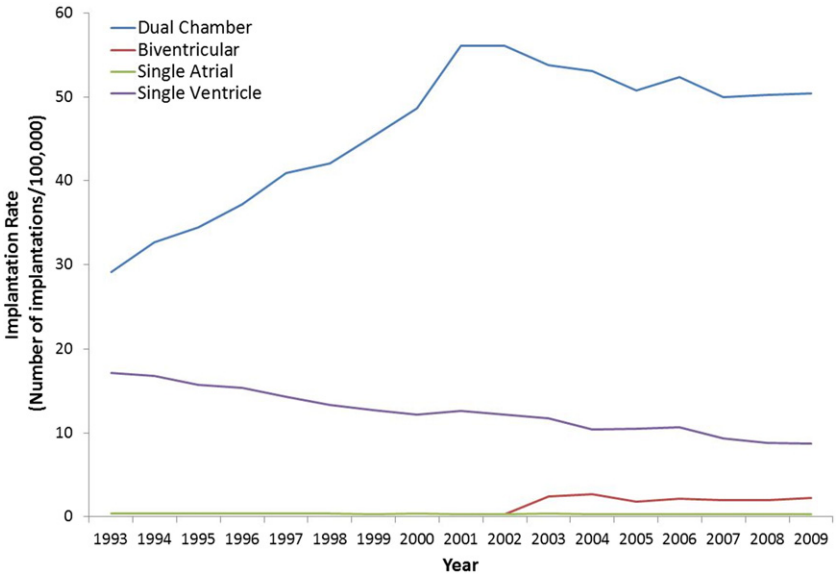

Figure 1 Pacemaker Use in the United States From 1993 Through 2009

The rate of dual-chamber pacemaker implantation (number of implants/100,000 persons) has increased over time until 2001, when use reached a plateau. Biventricular pacemakers, introduced in 2002, have leveled off after their initial introduction, whereas the use of single-chamber atrial pacemakers remains low.

women received DDD pacemakers, whereas 21% received VVI pacemakers, 0.6% received AAI pacemakers, and 0.6% received BiV pacemakers.

The mean age at implantation increased over time (Fig. 2). Those receiving VVI pacemakers were older than DDD patients ($p < 0.0001$). In 1993, DDD patients averaged 73.3 years of age, which increased to 75.4 years of age in 2009 ($p < 0.0001$). By contrast, in 1993, VVI patients were 77.5 years of age, which increased to 80.1 years of age in 2009 ($p < 0.0001$). The BiV patients also increased in age from 71.8 years in 2002 to 74.7 years in 2009 ($p < 0.0001$).

Trends based on type of hospital and insurance. The influence of hospital location was analyzed by evaluating pacemaker use in rural hospitals, urban nonteaching hospitals, and urban teaching hospitals. The use of DDD devices was higher in urban nonteaching hospitals (79%) compared with urban teaching hospitals (76%) and rural hospitals (73%), ($p < 0.01$). Patients with private insurance (83%) more commonly received DDD devices than Medicaid (79%) or Medicare (75%) patients ($p < 0.001$). To analyze further the impact of insurance type, the use of DDD pacemakers was evaluated after adjusting for factors such as age, sex, race, calendar year, urban or rural hospital location, and hospital size. After controlling for these factors, Medicaid patients were less likely than Medicare patients (hazard ratio: 0.84, 95% confidence interval: 0.79 to 0.886, $p < 0.001$), whereas private insurance patients were more likely than Medicare patients (hazard ratio: 1.205, 95% confidence interval: 1.165 to 1.247, $p < 0.001$) to receive DDD pacemakers.

Trends in patient comorbid conditions. Patient comorbidities were analyzed by measuring the average CCI for each calendar year. The patient level of comorbidity increased over time for all types of pacemakers. In 1993, the average CCI was 0.6 ± 0.9 for DDD patients versus 0.6 ± 1.0 for VVI patients. By contrast, in 2009, DDD patients had a CCI of 1.5 ± 1.5, whereas VVI patients had a CCI of 1.6 ± 1.6. The complexity of the patient's condition was measured by determining the number of patients with a CCI of more than 2. In 1993, a CCI of more than was 2 present in 14.1% of VVI patients, which increased to 45.1% in 2009. A similar trend was seen in the DDD group. In 1993, 13.5% of patients had a CCI of more than 2, which increased to 42.4% in 2009.

Pacemaker implantation trends in patients with sinus node dysfunction. We evaluated the impact of the diagnosis of sick sinus dysfunction on device use by analyzing pacemaker patients with codes 427.81 (sick sinus syndrome) and 426.6 (sinoatrial block) (Fig. 3). In this subgroup, DDD use increased, whereas VVI use decreased. By 2009, more than 80% of patients with sinus node dysfunction received a DDD pacemaker. Therefore, the diagnosis of sinus node dysfunction did not seem to have an impact on the type of device implanted.

Economic trends in pacemaker implantation. We queried the NIS to determine hospital charges associated with pacemaker insertion as an indicator of economic cost. Total hospital charges associated with pacemaker procedures increased during the study period (Fig. 4). Hospital charges in 2011 dollars increased by 45.3% from $53,693 in 1993 to $78,015 in 2009.

Discussion

The major findings of this analysis of a large national database are: 1) permanent pacemaker implantations in the United States have increased; 2) use plateaued in 2001; 3) use of dual-chamber pacemakers increased, whereas that

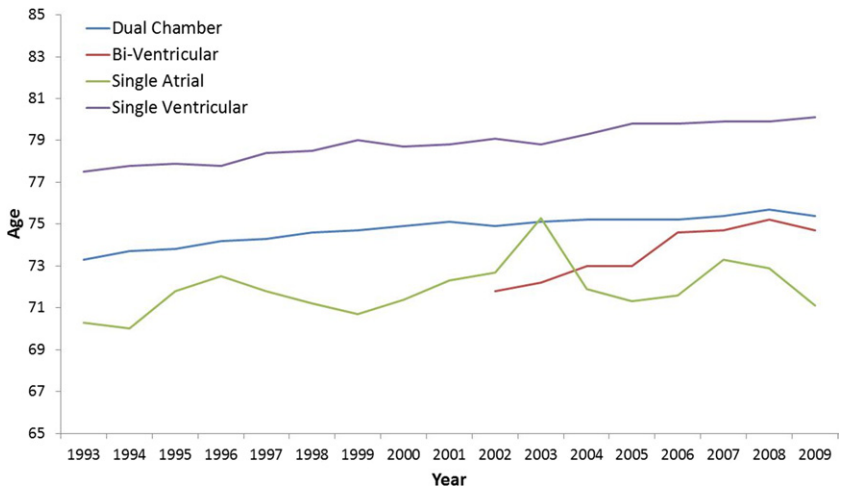

Figure 2 Age of Pacemaker Patients at Time of Implantation

The average age of pacemaker patients has increased slowly over time. Patients with single-ventricular pacemakers are older than those with dual-chamber pacemakers.

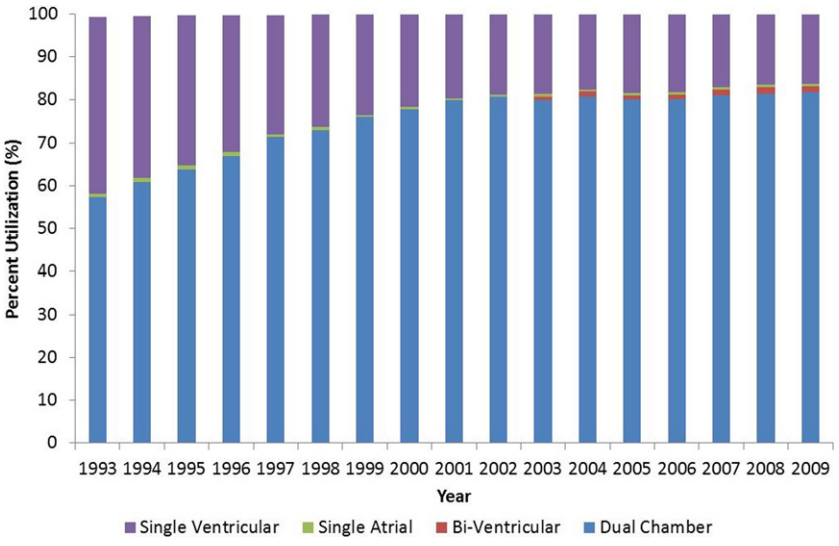

Figure 3 Use of Pacemakers in Patients Paced for Sinus Node Dysfunction

The distribution of pacemaker type in patients paced for sinus node dysfunction is similar to that of the group as a whole.

of single-chamber VVI pacemakers decreased, and DDD pacemakers now represent more than 80% of all pacemaker implantations; 4) pacemaker patients are becoming older and have a greater number of medical comorbidities; 5) use was impacted by the type of hospital and health insurance; and 6) these trends had financial implications as hospital charges increased.

Trends in permanent pacemaker implantation. There has been an increase in the annual pacemaker implantation rate (number of implants/100,000 persons) since 1993. However, this rate has plateaued since 2001. The 2005 World Survey of Cardiac Pacing confirmed this trend, finding that new implants in the United States were 786 per million in 2001 and 752 per 1 million in 2005 (2). Our

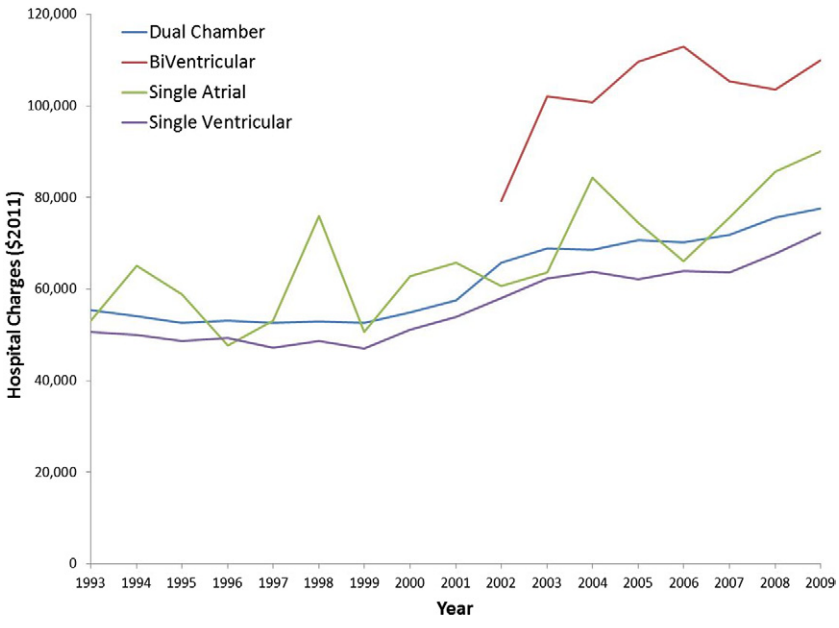

Figure 4 Hospital Charges Associated With Permanent Pacemaker Implantation From 1993 Through 2009 (in $2011)

The hospital charges associated with pacemaker implantation have increased over time.

previous study showed that overall pacemaker implantation peaked in 2001, whereas the overall use of cardiac implantable electronic devices continued to increase through 2006, driven by the marked increase in implantable cardioverter defibrillators implantation and introduction of cardiac resynchronization therapy (1).

Use of dual-chamber pacemakers. Dual-chamber technology has been adopted as the technology of choice in the United States. This technology represents an advance over single-chamber ventricular demand pacemakers. Current DDD pacemakers provide bradycardia support at the lower rate limit, while maintaining AV synchrony, as well as rate responsiveness at faster heart rates by tracking the intrinsic P wave. At the same time, current pacemaker algorithms minimize ventricular pacing by allowing intrinsic AV conduction (6). In our study, the rate of use of dual chamber pacing was similar for all patients, regardless of the indication for pacing.

The shift in use to dual chamber technology likely reflects improvements in lead and pacemaker design, as well as results of clinical trials that highlight the benefits of atrial-based pacing. Clinical trials comparing atrial-based with ventricular-based pacing demonstrate that atrial-based pacing prevents pacemaker syndrome, reduces the incidence of atrial fibrillation, decreases the incidence of congestive heart failure, improves quality of life, and reduces stroke (7–12). Based on these trials, the American College of Cardiology/American Heart Association/Heart Rhythm Society 2008 guidelines recommended dual-chamber pacing for the treatment of symptomatic bradycardia in patients who were in sinus rhythm and in whom atrioventricular synchrony and rate responsiveness were desirable (13). This represents most patients referred for cardiac pacing. Our observed shift toward dual-chamber technology could be a response to these clinical trials. Therefore, the National Coverage Determination for pacing, which emphasized single-chamber pacing and was last modified in 1985, is not in line with contemporary clinical practice.

Demographics of pacemaker patients. Pacemaker patients generally are elderly with associated medical comorbidities. Our study confirms that pacemakers are being implanted later in life in patients with many medical comorbidities. These findings are consistent with the 30-year study of pacemaker recipients in Olmstead County, Minnesota, where the age adjusted CCI increased from 3.15 to 4.60 ($p < 0.0001$) (3). An increasing CCI value had an adverse effect on prognosis after pacemaker implantation.

Implantation trends: influence of health insurance and hospital type. Pacemaker selection likely is influenced by factors other than the patient's age or associated medical conditions. Lamas et al. (14) analyzed a cohort of pacemaker recipients sampled from 20% of all Medicare beneficiaries over a 2-year period. Patients referred to large, urban teaching hospitals were more likely to receive dual-chamber pacemakers. In addition, Medicaid patients were less likely to receive a dual-chamber pacemaker (odds ratio: 0.78, 95% confidence interval: 0.71 to 0.86). Similarly, we found that type of insurance and implanting hospital impact pacemaker selection. The reasons for these disparities cannot be readily explained by our study.

Financial implications of pacemaker use. Finally, we observed that hospital charges are increasing, despite a decrease in the length of stay. Improvements in technology, often associated with dual-chamber pacing, come at a higher cost. It is unclear whether these costs will continue to rise and to what extent the healthcare system can withstand this financial burden.

Study limitations. The present analysis used the NIS, which is a national survey of hospital discharges and may underestimate total pacemaker implantation rate, because it does not capture outpatient procedures. In addition, the NIS suffers from the absence of clinical data. Nonetheless, this large database represents national trends in hospitalized patients.

Conclusions

In summary, pacemaker implantation in the United States has increased over a 17-year period. Patients are older and have more medical comorbidities. The vast majority of pacemakers are dual-chamber pacemakers, regardless of the indication for pacing. There are disparities in the use of dual-chamber pacing, based on the type of hospital and insurance. The costs associated with pacemaker implantation are rising as well. These findings have important implications for future healthcare policy decisions.

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Key Words: healthcare policy ■ permanent pacemaker ■ sick sinus syndrome.